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The feasibility and acceptability of acceptance and commitment therapy for depression and/or anxiety during pregnancy

Submission date
02/02/2026

Recruitment status
No longer recruiting

Registration date
03/02/2026

Overall study status
Ongoing

Last Edited
01/06/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Mental health conditions are highly prevalent in low to middle-income countries, particularly during the perinatal period. In Pakistan, rates of perinatal depression and anxiety have been reported at around 37% and 39%. There is a need for psychological interventions to support mothers and families impacted by perinatal depression and anxiety. Acceptance and Commitment Therapy for Perinatal Mental Health (ACT-PNMH) has been developed to meet this need. ACT-PNMH is an evidence-based intervention designed to improve symptoms of depression and anxiety during pregnancy and the postnatal period. We are testing ACT-PNMH in the NUR study to understand if the intervention and the methods that we use for the evaluation are helpful and acceptable for pregnant women in Pakistan. We also hope to explore if ACT influences mothers' mental health in the postnatal period and their relationship with their baby. To do this, we will compare the outcomes of women who received ACT-PNMH with those who received treatment as usual (TAU). TAU is the standard antenatal care delivered in the area where you live.

Who can participate?
Pregnant women aged 18 years and above with psychological distress, anxiety or depression

What does the study involve?
We will deliver ACT-PNMH over eight consecutive weeks to groups of 8-12 women in community venues. ACT-PNMH will be delivered by healthcare professionals in Pakistan who have been trained in the intervention by the team that developed ACT-PNMH from Cardiff University, Wales, UK.
When meeting with your healthcare provider, you will be invited to take part in the study, and you will be provided with information to make an informed decision about participating or not. If you are interested in taking part, you will be asked to complete a consent to contact form and a screening questionnaire about your mental health and pregnancy. If you are eligible to take part in the NUR study, you will then be contacted by a researcher from the study team, who can answer any further questions you may have about the study. If you are happy to take part, you will then complete a consent form and the baseline questionnaire about your mental health and

pregnancy. You will then be placed, at random, into either the 8-week ACT-PNMH intervention or the treatment-as-usual group (TAU).
If you are allocated to the ACT-PNMH intervention or the TAU group, you will be asked to complete questionnaires 9 weeks later and again when your baby is 3 months old. You will also be asked to complete a brief video recording of you playing with your baby at 3 months postpartum, and we will ask you some brief questions about your baby's development. If you are allocated to the ACT-PNMH intervention, you will be asked to complete an additional brief questionnaire at session three and at session five. We will also invite you to participate in semi-structured interviews about your experience of taking part in the NUR study and of the ACT-PNMH intervention. If you are allocated to the treatment-as-usual group, you will be offered the ACT-PNMH intervention after your baby is 3 months old.

What are the possible benefits and risks of participating?
Currently, there is a lack of information about the helpfulness and long-term benefits of psychological interventions for the treatment of anxiety and depression in Pakistan, compared to usual care. Regardless of the group you will be randomised into, your input will help us learn about how best to support perinatal women who experience depression and anxiety and how best to evaluate psychological interventions in Pakistan. As a small token of our appreciation for taking part, we can offer you 2000 Rupees for completing the baseline questionnaire, 2000 Rupees for completing the 9-week follow-up questionnaire, and 2000 Rupees for completing the 3-month postpartum assessment.
We are not expecting there to be any disadvantages or risks to you or your baby from taking part in the NUR study. You may feel anxious before sessions or tired after taking part in sessions. This may also be the case when completing the questionnaires. We will do everything we can to minimise or prevent this, and you may notice that the anxiety lessens as you get to know the ACT-PNMH facilitators over the 8 weeks.

Where is the study run from?
Health Services Academy (Pakistan)

When is the study starting and how long is it expected to run for?
February 2026 to January 2027

Who is funding the study?
Higher Education Funding Council for Wales, MEDR, through Official Development Assistance funding

Who is the main contact?
Dr Samina Naeem Khalid (drsamina@hsa.edu.pk) is the main contact for the study in Pakistan
Dr Cerith Waters (waterscs@cardiff.ac.uk) is the main contact for the study in Wales, UK

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Additional identifiers

Study information

Scientific Title

The NUR study: a pilot randomised controlled trial and Nested process evaluation stUdy of acceptance and commitment theRapy for pregnant women with antenatal depression and/or anxiety in Pakistan

Acronym
NUR

Study objectives
Primary objectives (feasibility and acceptability):
The primary objective is to evaluate the feasibility and acceptability of the pilot RCT design and of the culturally adapted Acceptance and Commitment Therapy for Perinatal Mental Health (ACT-for-PNMH) intervention.
1. Feasibility of recruitment and retention: determine whether eligible pregnant women can be successfully identified, approached, recruited, randomised, and retained throughout the study.
2. Feasibility of intervention delivery: assess whether participants can attend the ACT-for-PNMH sessions as planned, including session attendance, completion, and reasons for non-attendance.
3. Data feasibility: evaluate whether outcome measures and process measures can be completed reliably, with acceptable levels of data completeness and minimal missing data.
4. Intervention fidelity and adherence: assess whether the ACT-for-PNMH intervention can be delivered as intended, including adherence to the intervention manual and facilitator fidelity.
5. Acceptability to participants and facilitators: explore the acceptability of the intervention, study procedures, and research processes from the perspectives of participants and facilitators.

Secondary objectives (preliminary efficacy):
To explore potential signals of clinical improvement and estimate variability to inform future sample size calculations.
1. Psychological symptom change: explore initial trends and variability in psychological distress, depression, and anxiety symptoms, e.g., psychological distress (CORE-10), depression (PHQ-9), and anxiety (GAD-7).
2. Functional outcomes: explore trends and variability in maternal functioning, e.g., CORE-10, quality of life (EUROQoL).
3. Intervention mechanisms: explore trends and variability in ACT-PNMH intervention mechanisms, including psychological flexibility (Multidimensional Psychological Flexibility Inventory [MPFI]) and the therapeutic alliance (Working Alliance Inventory – Short Form [WAI-SF]).
4. Impact on childbirth, infant and mother-infant relationship: explore trends and variability in outcomes on childbirth (Birth Experiences Questionnaire [BEQ]), infant (WHO-Global Scales for Early Development [GSED]) and mother-infant relationship outcomes (Postpartum Bonding Questionnaire [PBQ]; audio-visual recording of mother-infant interaction).

Process evaluation objectives:
To understand how the intervention and the RCT procedures operate within real-world antenatal care settings and identify factors that may support or hinder scalability.
1. Implementation in routine care: examine how the ACT-for-PNMH intervention is delivered within existing healthcare systems and identify organisational, structural, and contextual factors affecting implementation.
2. Mechanisms of impact: explore how participants engage with ACT-for-PNMH components and how these may contribute to changes in psychological or functional outcomes.
3. Contextual influences: identify barriers and facilitators to delivery, including cultural, logistical, and system-level factors that may influence future scalability and sustainability.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/01/2026, Health Services Academy, Institutional Ethical Review Committee (PM National Health Complex, Park Road, Chak, Shahzad, Islamabad,, 44000, Pakistan; (92-51) 9255590.94; academy@hsa.edu.pk), ref: No.7.82/IERC-HSA/2022-241

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Clinically significant antenatal depression and/or anxiety symptoms in the second trimester of pregnancy

Interventions
Computer-generated, 1:1 allocation to ACT-PNMH plus usual care or usual care alone, stratified by site and baseline severity.

Intervention:
Eight weekly sessions (90-minute duration) of group-delivered ACT-PNMH by trained therapists, plus usual care. The original ACT-PNMH manual (Waters et al., 2020) has been translated and culturally adapted for the Urdu-speaking population of Pakistan (Maqsood et al., 2025). Intervention sessions will be delivered in person or remotely (e.g. via videoconferencing) if a participant cannot attend a given group session.

Comparator:
Usual care provided by standard antenatal mental health or primary care services. There is no standard model of care for antenatal depression and anxiety in Pakistan, but could include support provided by general practitioners, midwives and/or referrals to mental health services provided by psychologists and/or psychiatrists.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rates measured using number approached, number declined, number consented at baseline

2. Reasons for declining RCT and/or intervention measured using qualitative methods at baseline

3. Intervention completion rates, defined as attending 4+ sessions, measured using descriptive statistics (%) at weekly and post-treatment

4. Mean, median and modal number of sessions attended measured using mean, median and mode at weekly sessions during intervention delivery and collated at post-treatment

5. Reasons for missing a session measured using a checklist at weekly sessions during intervention delivery and post-treatment

6. Reasons for dropping out of intervention before completion measured using a checklist at weekly sessions during intervention delivery and post-treatment

7. The completeness of outcome measures and data collection measured using % at baseline, post-treatment and 3-month follow-up

8. ACT-for-PNMH adherence measured using % of sessions that are adherent to the manual assessed at weekly sessions during intervention delivery

9. ACT fidelity ratings measured using the ACT Fidelity Measure (ACT-FM) at weekly sessions during intervention delivery

10. The acceptability of the ACT-for-PNMH intervention measured using Likert rating scales (range 0-5) at sessions 3, 5 and 8

11. Acceptability of the RCT design measured using Likert rating scales (range 0-5) at baseline and post-treatment

12. Adverse events measured using a checklist at baseline, weekly during intervention delivery, at post-treatment, and at 3 months postpartum

Key secondary outcome(s)

Completion date
31/01/2027

Eligibility

Key inclusion criteria
1. Age: 18 years or older
2. Gestation: 16–28 weeks at the start of the intervention
3. Consent: able to provide informed consent
4. Psychological distress: clinical range on the Clinical Outcomes in Routine Evaluation 10 (CORE-

10) score ≥11 and either the Patient Health Questionnaire-9 (PHQ-9) score ≥10 (depression) and /or General Anxiety Disorder-7 (GAD-7) score ≥8 (anxiety)
5. Intervention attendance: able to attend the intervention sessions

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Female

Total final enrolment
76

Key exclusion criteria
1. Severe psychiatric conditions: current psychosis or bipolar disorder
2. Substance use: current substance dependence
3. Concurrent psychological treatment: receiving another structured psychological intervention at baseline
4. Medication changes: change in psychotropic medication within one month prior to randomisation
5. Suicidal risk: suicidal intent or high risk at baseline assessment
6. Other conditions: any medical or obstetric condition that would prevent participation in the intervention or compromise safety (e.g., severe pregnancy complications)

Date of first enrolment
06/02/2026

Date of final enrolment
16/05/2026

Locations

Countries of recruitment
Pakistan

Study participating centre
Health Services Academy, Ministry of National Health Services
PM National Health Complex, Park Road, Chak, Shahzad

Islamabad
Pakistan
44000

Sponsor information

Organisation
Health Services Academy Islamabad, Ministry of National Health Services

Funder(s)

Funder type

Funder Name
Medr

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 5	30/01/2026	01/06/2026	No	No